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K981885

13.0 510(k) SUMMARY OF SAFETY AND EFFICACY

Submitter: Sunrise Medical – Mobility Products Division
7477 East Dry Creek Parkway
Longmont, CO 80503
Phone (303) 218-4595 Fax (209) 218-4565

Rebecca Andersen
Date: November 5, 1998

Name(s) of the device(s): Sunrise 3 Wheel Scooter

Identification of predicate device(s):

1) Quickie P190 by Sunrise Medical
2) Quickie P120 by Sunrise Medical
3) Sabre by Everest & Jennings
4) Ranger II by Invacare Corporation

Description of the device:
The Three Wheeled mid Range Scooter is a medium duty, conventional, rear wheel drive, rigid frame power Vehicle. The armrests of the seat are adjustable. The seat may be repositioned from front to back and chair height can be adjusted up and down. There are many kinds of accessories that are commonly sold after market. These accessories include canopies, crutch holders, cup holders, baskets etc.

Like most scooters, the tiller and throttle controls are the user interface. They transfer the rider's intentions to command the device. When the control is activated, or moved out of neutral position, the motor brake is energized and released, allowing the scooter to move in the appropriate direction. When the activation device is released, the scooter slows to a stop and the motor brake is automatically re-engaged. These dynamic "on command" brakes allow the user to stop by letting go of the activation device.

If the scooter looses power, the motor brake is automatically engaged and the scooter comes to a stop. To prevent the rider from becoming stranded, the scooter may be pushed. The design incorporates a "free wheel" device motor lock disengagement device. This device allows the drive train to be manually disengaged, enabling the scooter to be pushed. It should be noted that the scooter would not have electronic brakes when in the "free wheel" mode.

The controller is microprocessor based and program-able. It is pre-programmed at the manufacturer to meet Sunrise specifications. **This controller is currently used on selected models of the Sunrise scooters under K880425.** Drive characteristics that are pre set are:

forward/reverse acceleration	forward/reverse deceleration
forward speed	reverse speed

The controller also has manual reset circuit breakers. These adjustments and features are similar to all standard scooter controllers.

The scooters have excellent performance indoors for use in shopping malls or grocery stores, and handle very well outdoors on paved surfaces, compact gravel, dry grass or other firm surfaces free from large obstacles. The Sunrise Scooter is designed to be maneuverable yet stable and powerful. That makes it the ideal moderate duty "Get out there" Scooter.

Intended use:

Sunrise scooters empower physically challenged persons by providing a means of mobility.

Comparison of device characteristics to predicate(s):

This device has similar technological characteristics as the predicated devices. They all use steel and aluminum in their frame and components, and standard foams and covers for the slings and backs. Microprocessors are typically used with a programmable controller, and the rider controls the chair using a joystick or other equivalent command mode. Motors use permanent magnets, employing 24 volt D.C., with rechargeable deep cycle batteries for an energy source. The operating speeds and maneuverability are substantially equivalent, and recommended for indoor or moderate outdoor use. The standard accessories and components are common to all power wheel chair lines.

Testing:

This device has been tested to both ISO7176 and ANSI/RESNA Wheelchair Standards. They include:

Static Stability
Dynamic Stability
Effectiveness of Brakes
Energy consumption
Overall Dimensions
Maximum Speed acceleration and retardation
Static Impact
Fatigue Strength
Climatic Test
Obstacle Climbing Ability
Testing of Power and Control System
EMC Testing

We have also tested to the Proposed:

Addition to ANSI/RESNA W/C 14 Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters Version 1.5 Dated 1/11/94

ISO EMC Draft Standard 7176-14 Rifled Draft ISO EMC Group Proposal Electromagnetic Compatibility Addition Dated 4/3/95 Regarding Electromagnetic Compatibility Requirements for Powered Wheelchairs and Motorized Scooters.

Safety:
An analysis of complaints against Sunrise power chairs and scooters was completed and charted. This analysis was supported by a literature search, which was conducted by a third party to determine the number of complaints, MDR's and recalls that have been reported to the FDA concerning wheelchairs in general. This information was summarized, and presented in a Management Review report dated 2/20/97. Subsequent complaints against Sunrise are presented in a chart entitled "Total Sunrise Medical Power Product Complaints". The data and charts are included as Attachment 13 - A. The analysis demonstrated common issues across all manufacturer product lines, and varying levels approximately comparable to relative market share. Sunrise has concluded that there are no use issues exclusive to Sunrise chairs at this time.

Efficacy
Articles are being provided on the use and efficacy of power wheelchairs.

1) "Power Wheelchair Comparison", Ian Denison, 14th International Seating Symposium Proceedings, pp. 113 – 116, February 1998.

2) "Front, Back or in the Middle: Understanding Mid-Wheel Drive", Mark Greig, Sunrise Horizons, Vol I, Number 4, pp. 6 – 7, February 1998.

3) "Dynamic Wheelchair Stability: Reliability of an Ordinal Scale", R. L. Kirby, D. A. MacLeod, R. E. Duggan, et. al., Proceedings of RESNA '97, pp. 237 – 239.

4) "When Wheelchairs Tip backwards Beyond Their Stability Limits", R. L. Kirby, M. DiPersio, and D. A. MacLeod, Proceedings of RESNA '96, pp. 180 – 182.

5) "Effect on Wheelchair Stability and Maneuverability of Varying the Position of the rear Antitip Device: A Theoretical Model", R. L. Kirby, A. V. Thoren, B. D. Ashton, and S. A. Ackroyd-Stolarz, Proceedings of RESNA '93, pp. 313 – 315.

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Conclusion: The Sunrise Scooter Series is substantially equivalent to the predicated devices listed in this 510(k); the technology and construction of the P190R does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1998

Ms. Rebecca Andersen
Vice President, Quality/Regulatory Affairs
Sunrise Medical
Mobility Products Division
7477A East Dry Creek Parkway
Longmont, Colorado 80503

Re: K981885
Trade Name: Sunrise 3 Wheel Scooter
Regulatory Class: II
Product Code: INI
Dated: October 1, 1998
Received: October 7, 1998

Dear Ms. Andersen:

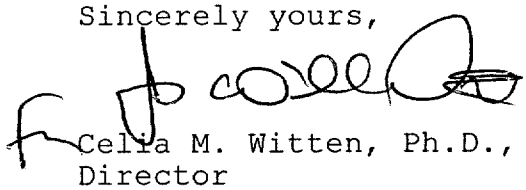
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Sunrise scooters empower physically challenged persons by providing a means of mobility.

510(k) number: K981885

Device name: SUNRISE SCOOTER

Concurrence of CDRH, Office of Device Evaluation (ODE)

☐ Prescription use (per 21 CFR801.109)

☑ Over-the-counter use

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981885